## Pfizer Inc.

235 East 42<sup>nd</sup> Street New York, NY 10017



March 20, 2020

Office of the Vermont Attorney General

## Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

Dear Office of the Vermont Attorney General,

Pfizer Inc. ("Pfizer") is issuing this notice pursuant to 18 V.S.A. § 4637(c), which requires prescription drug manufacturers to provide the Office of the Attorney General (the "Office") with certain information following the release of a drug in the commercial market whose Wholesale Acquisition Cost ("WAC") exceeds the threshold set for a specialty drug under the Medicare Part D Program.

Pfizer released TRAZIMERA™ (trastuzumab-qyyp) for injection into the commercial market on February 18, 2020. Pfizer anticipates TRAZIMERA'S ™ WAC to exceed the threshold set for a specialty drug under the Medicare Part D Program.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Pfizer is not aware of any guidance issued by the Office or any Vermont regulation that defines "release of the drug in the commercial market" for the purpose of 18 V.S.A. § 4637.

As a result, Pfizer considers a drug to be "release[d] . . . in the commercial market" when Pfizer publishes a trade letter to wholesale customers announcing the introduction of the new drug and begins accepting orders for the drug.

Statutory Requirement	Reporting Information
A description of the marketing and	Pfizer does not believe this information is publicly
pricing plans used in the launch of the	available and has not released this information in the
new drug in the United States and	public domain. Accordingly, Pfizer is limiting its
internationally.	response to this item pursuant to 18 V.S.A. § 4637(d).
	Based on our internal estimates of the size of the
The estimated volume of patients that	trastuzumab market based on Herceptin's usage
may be prescribed the drug.	across therapeutic areas, we estimate 64,000 patients
	currently being treated on Herceptin.
Was the drug granted breakthrough	
therapy designation by the federal	TRAZIMERA™ did not receive breakthrough
Food and Drug Administration prior to	designation by the federal FDA.
final approval?	

Did the drug receive a priority review by the federal Food and Drug Administration prior to final approval?	TRAZIMERA™ did not receive priority review by the federal FDA.
The date and price of acquisition if the drug was not developed by the	N/A
manufacturer.	

In the event Vermont S. 92 and the laws it implements, including 18 V.S.A. § 4637, are found invalid, Pfizer reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Pfizer does not waive any legal claims or legal rights related to potential constitutional defects with Vermont S. 92.

For any questions concerning this notification please contact: <a href="mailto:StateLawReporting@Pfizer.com">StateLawReporting@Pfizer.com</a>